

## Vergleichende Evaluierung der Sensitivität von SARS-CoV-2-Antigenschnelltests Comparative evaluation of the sensitivities of SARSCoV-2 antigen rapid tests

### Ziel

Vergleich verschiedener Antigenschnelltests mit einheitlichem Probenmaterial

### Aim

Comparison of different antigen rapid tests using uniform sample material

### Material

Pools von naso- und oropharyngealen Abstrichen, die als Prüfproben für ein Panel verwendet werden.

Trockene Tupfer wurden direkt in PBS eluiert, feuchte Tupfer waren bereits in Transportmedium unterschiedlicher Zusammensetzung. Pools sind zufällige Mischungen aus bis zu 10 Proben vergleichbarer Cq Werte, die 1:10 in negativen Proben in PBS verdünnt wurden (Cq = Quantifizierungszyklus; auch als CT = cycle threshold bezeichnet). Die Cq Werte eines Pools wurden mit verschiedenen PCR Assays bestimmt und die mutmaßliche Anzahl an RNA-Kopien mit Hilfe des INSTAND Standards berechnet. Bei den verwendeten PCRs entspricht ein Cq Wert von 25 etwa 10<sup>6</sup> RNA Kopien/mL. Vermehrung des Virus in Zellkultur wurde als mögliches Korrelat für Infektiosität als weiteres Merkmal der Proben bestimmt.

Aufgrund der hohen Anzahl an zu überprüfenden Tests mussten einzelne Proben des ersten Prüfpanels ersetzt werden (Panel 1 Versionen 1 und 2) bzw. in analoger Weise ein neues Panel (Panel 2) hergestellt werden. Für Panel 1 Versionen 1 bzw. 2 wurden 18 bzw. 17 Proben mit Cq ≤25, 23 Proben mit Cq 25 – 30 und 9 bzw. 10 Proben mit Cq ≥30 eingesetzt. Panel 2 setzt sich aus 20 Proben mit Cq ≤25, 20 Proben mit Cq 25 – 30 und 10 Proben mit Cq ≥30 zusammen.

### Durchführung

Die Pools wurden aliquotiert, eingefroren, versendet, und zur Evaluierung der Tests aufgetaut. Für jeden Test wurden 50 µl eines Pools (Panel 1 V1, V2) bzw. 25 µl (Panel 2) mit den vom Test bereitgestellten Komponenten z. B. Tupfer und Puffer, analysiert. Wenn ein Test für mehrere Probentypen ausgelegt war (z. B. nasopharyngeal, nasal, Speichel, etc.),

### Material

Pools from nasopharyngeal and oropharyngeal swabs which are used as test specimens included in an evaluation panel.

Dry swabs were directly eluted in PBS; moist swabs were already included in the transport media of various compositions. Pools are random mixtures obtained from up to 10 samples of comparable Cq values diluted 1:10 in negative samples in PBS (Cq = Quantification cycle; also reported as CT = cycle threshold). The Cq values of a pool were determined by means of different PCR assays, and the putative number of RNA copies calculated with the aid of the INSTAND standard. In the case of the PCRs used, a Cq value of 25 corresponds to around 10<sup>6</sup> RNA copies/mL. The replication of the virus in cell culture as another characteristic of the samples was determined as a possible correlate for infectiousness.

Due to the high number of tests under evaluation few specimens of the first panel were replaced (resulting in panel 1 versions 1 and 2), and a new panel (panel 2) was manufactured in analogous manner. For panel 1 versions 1 and 2, 18 or 17 samples, respectively, were characterized as Cq ≤25, 23 samples as Cq 25-30, and 9 or 10 samples, respectively, as Cq ≥30; the composition of panel 2 is: 20 samples with Cq ≤25, 20 samples with Cq 25-30, and 10 samples with Cq ≥30.

### Method

The pools were aliquoted, frozen, shipped, and thawed for evaluation of the tests. For each test, 50µl of the pool (panel 1 versions 1 and 2), or 25µl (panel 2) were analysed using the components of the test provided, e.g. swabs and buffer. In case of tests designed for various sample types (e.g. nasopharyngeal, nasal, saliva, etc), the test specific swab dedicated for



wurde der testspezifische Tupfer für die nasopharyngeale Probennahme verwendet. An der vergleichenden Evaluierung beteiligte Labors sind u. a. Robert Koch-Institut, Paul-Ehrlich-Institut, Konsiliarlabor für Coronaviren (Charité), Institut für Mikrobiologie der Bundeswehr.

## Zusammenfassung

Diese vergleichende Evaluierung einer großen Anzahl von SARS-CoV-2 Antigenschnelltests (point of care tests; POCT) verschiedenen Designs und verschiedener Hersteller mit einem einheitlichen Probenstet ermöglicht einen Überblick über den derzeitigen Stand der Technik hinsichtlich ihrer Sensitivität. Der derzeitige Stand der Technik wurde einer Mindestsensitivität von 75 % für die Pools mit einem Cq  $\leq 25$  gleichgesetzt. Die Ergebnisse lassen keine Rückschlüsse auf die Spezifität der Tests zu.

**Tabelle 1** fasst die Ergebnisse der Antigenschnelltests zusammen, die als „dem Stand der Technik entsprechend“ bewertet wurden (alphabetische Reihenfolge der Hersteller).

**Tabelle 2** fasst die Ergebnisse derjenigen Tests zusammen, die das Sensitivitäts-Kriterium nicht erfüllten und aus der Liste des BfArM (erstattungsfähige Tests) gestrichen wurden (alphabetische Reihenfolge der Hersteller).

Der erste Teil der Evaluierung wurde bereits wissenschaftlich veröffentlicht (1); in dieser Publikation sind weitere Details der vergleichenden Evaluierung zusammengefasst.

**Es sei ausdrücklich darauf hingewiesen, dass diese vergleichende Evaluierung nur eine Stichprobe der beim BfArM gelisteten und somit erstattungsfähigen SARS-CoV-2 Antigenschnelltests berücksichtigen kann, und manche Tests bislang (noch) nicht berücksichtigt werden konnten, trotz entsprechendem Interesse seitens Herstellern / Vertreibern.**

## Kontakt:

E-Mail: sarscov2ivd@pei.de

nasopharyngeal samples was used.

Laboratories participating in the comparative evaluation included the Robert Koch-Institut, the Paul-Ehrlich-Institut, the reference laboratory for coronaviruses (Charité), and the Institute for Microbiology of the German Army (Bundeswehr).

## Summary

This comparative evaluation of a large number of SARS-CoV-2 rapid antigen tests (point of care tests; POCT) of different designs and manufacturers using the uniform sample sets allows an overview of the current state of the art regarding sensitivity.

The current state of the art was defined as corresponding to a minimal sensitivity of 75% for the pools with Cq  $\leq 25$ . The results do not allow any conclusions regarding specificity of the tests.

**Table 1** summarizes the results of those POCTs assessed as reflecting the current state of the art (alphabetical order of manufacturers).

**Table 2** summarizes the results of those POCT (alphabetical order of manufacturers) which do not fulfill the sensitivity criteria and consequently are deleted from the list of reimbursable tests (see the homepage of Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM)).

The first part of this evaluation has already been published (1); this publication summarizes further details of the comparative evaluation.

**You should be aware that this comparative evaluation can only cover a random sample of the SARS-CoV-2 rapid antigen tests listed by the BfArM, thus eligible for reimbursement, and that few other products could not (yet) be taken into account, despite the interests on the part of the manufacturers/distributors.**

## Contact

Email: sarscov2ivd@pei.de

(1) Scheiblaue Heinrich, Filomena Angela, Nitsche Andreas, Puyskens Andreas, Corman Victor M, Drosten Christian, Zwirgmaier Karin, Lange Constanze, Emmerich Petra, Müller Michael, Knauer Olivia, Nübling C Micha. Comparative sensitivity evaluation for 122 CE-marked rapid diagnostic tests for SARS-CoV-2 antigen, Germany, September 2020 to April 2021. Euro Surveill. 2021;26(44):pii=2100441. <https://doi.org/10.2807/1560-7917.ES.2021.26.44.2100441>

## Ergebnisse der Vergleichende Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests / Results of the Comparative Evaluation of the Sensitivity of SARS-CoV-2 Antigen Rapid Tests

(sortiert in alphabetischer Reihenfolge der Hersteller / sorted in alphabetical order of manufacturers)

Stand vom / dated: 26.04.2022

### Tabelle 1: Ergebnisse der SARS-CoV-2 Antigenschnelltests, die das Sensitivitätskriterium erfüllen

Hinweis: Das Ergebnis der Evaluierung kann seitens BfArM auf baugleiche Produkte mit abweichendem Test-/ Herstellername oder andere Probentypen übertragen werden, dies gilt auch für Selbsttests. Diese baugleichen Produkte werden dann in den Listen des BfArM „Antigen-Tests nach § 1 Satz 1 Coronavirus-TestV zur professionellen Anwendung“ und „Antigen-Tests nach § 1 Satz 1 Coronavirus-TestV zur Eigenanwendung“ unter "Evaluierung PEI" ebenfalls mit „Ja“ gekennzeichnet.

### Table 1: SARS-CoV-2 antigen rapid diagnostic tests passing the sensitivity criteria

Note: The result of the evaluation can be transferred by BfArM to identical products with a different test/manufacture name or other sample types, this also applies to self-tests. These identical products are then also marked with "Ja" under "Evaluierung PEI" in the BfArM lists "Antigen tests according to § 1 paragraph 1 Coronavirus Test Regulation (TestV) for professional use" and "Antigen tests for SARS-CoV-2 according to § 1 sentence 1 Coronavirus Test Regulation (TestV) for self-testing".

| AT-Nr.    | AT-Nr.<br>Selbsttest # | Ref-Nr. *   | Hersteller                                  | Testname   | Zielantigen    | Sensitivität / Sensitivity |          |        |                     |                   |
|-----------|------------------------|-------------|---|--|----------------|----------------------------|----------|--------|---------------------|-------------------|
|           |                        |             |   |  |                | Cq ≤25                     | Cq 25-30 | Cq ≥30 | Gesamt-Sensitivität | Omikron Erkennung |
| AT-No.    | AT-No. self-test #     | ID-No. *    | Manufacturer                                | Test name  | target antigen |                            |          |        | total sensitivity   | bridging Prüfung  |
| AT005/20  |                        | 41FK10      | Abbott Rapid Diagnostics Jena GmbH          | Panbio™ COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)                     | N              | 100,0%                     | 60,9%    | 0,0%   | 64,0%               | Ja                |
| AT018/21  |                        | n.a.        | Abiotec                                     | Cora Gentest-19  | N              | 100,0%                     | 45,0%    | 0,0%   | 58,0%               | Ja                |
| AT084/21  |                        | ABT-IDTB367 | AccuBioTech Co.,Ltd.                        | Accu-Tell Rapid In-vitro Diagnostiktest                                    | N              | 100,0%                     | 75,0%    | 0,0%   | 70,0%               | Ja                |
| AT155/20  | AT1217/21              | L031-11815  | ACON Biotech (Hangzhou) Co., Ltd            | Flowflex SARS-CoV-2-Antigenschnelltest                                     | N              | 94,1%                      | 4,3%     | 0,0%   | 34,0%               | Ja                |
| AT1024/21 |                        | n.a.        | Acro Diagnostics Co., Ltd                   | SARS-CoV-2 Antigen Rapid Detection Kit (LFA)                               | N              | 100,0%                     | 100,0%   | 80,0%  | 96,0%               |                   |
| AT363/20  |                        | 840001      | Aesku Diagnostics GmbH                      | Aesku Rapid SARS-CoV-2 Rapid Test  | N              | 82,4%                      | 17,4%    | 0,0%   | 36,0%               | Ja                |
| AT181/21  |                        | 1166-25     | Affimedix                                   | TestNOW® COVID-19-Antigen-Test   | N              | 100,0%                     | 47,8%    | 0,0%   | 58,0%               | Ja                |
| AT303/20  |                        | RICOV2      | Amazing Biotech (Shanghai) Co., Ltd         | CoroVisio Covid-19 Ag Versieglungsrohrchen Teststreifen (Kolloidales Gold) | N              | 76,5%                      | 8,7%     | 0,0%   | 30,0%               | Ja                |
| AT033/20  |                        | RT2952      | Ameda Labordiagnostik GmbH                  | AMP Rapid Test SARS-CoV-2 Ag   | N              | 100,0%                     | 78,3%    | 0,0%   | 70,0%               |                   |
| AT412/21  |                        | MU00325     | Amper,Inc.                                  | Amper COVID-19 Antigen Rapid Testing Kit (Colloidal Gold)                  | N              | 100,0%                     | 100,0%   | 40,0%  | 88,0%               | Ja                |
| AT147/20  | AT1332/21 / AT1333/21  | A6061202    | Anbio (Xiamen) Biotechnology Co., Ltd       | Rapid Covid-19 Antigen Test (Colloidal Gold )                              | N              | 100,0%                     | 52,2%    | 0,0%   | 58,0%               | Ja                |
| AT031/20  | AT1190/21 / AT1288/21  | n.a.        | Anhui Deepblue Medical Technology Co., Ltd. | COVID-19 (SARS CoV-2) Antigen Test Kit (Colloidal Gold)                    | N              | 100,0%                     | 39,1%    | 0,0%   | 52,0%               | Ja                |
| AT785/21  |                        | FCB-103     | Anhui Formaster Biosci Co., Ltd             | New Coronavirus (COVID-19) Antigen Rapid Test                              | N              | 100,0%                     | 50,0%    | 10,0%  | 62,0%               | Ja                |
| AT518/20  |                        | A03-50-422  | Artron Laboratories Inc.                    | COVID-19 Antigentest   | N              | 100,0%                     | 95,0%    | 20,0%  | 82,0%               | Ja                |

| AT-Nr.                 | AT-Nr.<br>Selbsttest # | Ref-Nr. *    | Hersteller  | Testname   | Zielantigen    | Sensitivität / Sensitivity |          |        |   | Omikron<br>Erkennung<br>entsprechend der<br>Bridging Prüfung |
|------------------------|------------------------|--------------|---|--|----------------|----------------------------|----------|--------|---|--|
|                        |                        |              |   |  |                | Cq ≤25                     | Cq 25-30 | Cq ≥30 | Gesamt-<br>Sensitivität<br>total<br>sensitivity |  |
| AT-No.                 | AT-No. self-<br>test # | ID-No. *     | Manufacturer  | Test name  | target antigen |                            |          |        |   | Omicron detection<br>by bridging                             |
| AT431/20               |                        | AM3474-K     | ASAN PHARM.CO.,LTD.                                     | Asan Easy Test COVID-19 Ag   | N              | 100,0%                     | 69,6%    | 0,0%   | 66,0%   | Ja   |
| AT1030/21              | AT1354/21              | COV-S23      | Assure Tech (Hangzhou) Co.,Ltd                          | ECOTEST COVID-19 Antigen Rapid Test Device   | N              | 95,0%                      | 50,0%    | 0,0%   | 58,0%   | Ja   |
| AT791/21               |                        | MY28         | Asterion Otel Insaat Bilisim Medikal Maden Tic.Ltd.Sti. | AS-check COVID-19 Antigen Schnelltest  | N              | 85,0%                      | 5,0%     | 0,0%   | 36,0%   | Ja   |
| AT132/20               |                        | nCOV-500     | Atlas Link Technology Co.,Ltd.                          | Nova Test SARS-CoV-2 Antigen Rapid Test Kit  | N              | 100,0%                     | 60,9%    | 0,0%   | 62,0%   |  |
| AT441/20               |                        | 8004664      | Avalun  | Ksmart® SARS-COV2 Antigen Rapid Test   | N              | 94,1%                      | 13,0%    | 0,0%   | 38,0%   |  |
| AT374/20               |                        | 88 99 19     | AXIOM Gesellschaft für Diagnostica und Biochemica mbH   | Axiom Diagnostics COVID-19 Ag Schnelltest  | N              | 100,0%                     | 52,2%    | 0,0%   | 58,0%   |  |
| AT061/20               |                        | B62000       | Azure Biotech Inc.                                      | Dia Sure Covid-19 Antigen Rapid Test Device<br>(Nasopharyngeal/Oropharyngeal Swab) | N              | 76,5%                      | 13,0%    | 20,0%  | 36,0%   | Ja   |
| AT074/20               | AT1285/21<br>AT1286/21 | n.a.         | Beijing Beier Bioengineering Co., Ltd.                  | Covid-19 Antigen Schnelltest   | N              | 77,8%                      | 0,0%     | 0,0%   | 28,0%   | Ja   |
| AT967/21               |                        | P2311        | Beijing Homa Biological Engineering Co., Ltd.           | COVID-19 Antigen Test Kit  | N              | 100,0%                     | 35,0%    | 0,0%   | 54,0%   | Ja   |
| AT120/20               | AT1236/21              | n.a.         | Beijing Hotgen Biotech Co., Ltd.                        | Novel Coronavirus 2019-nCoV Antigen Test (Colloidal gold)                          | N              | 100,0%                     | 47,8%    | 0,0%   | 56,0%   | Ja   |
| AT205/20               |                        | C3042        | Beijing Jinwofu Bioengineering Technology Co.,Ltd.      | Jinwofu Novel Coronavirus (SARS-COV-2) Antigen Rapid Test Kit                      | N              | 100,0%                     | 50,0%    | 0,0%   | 60,0%   | Ja   |
| AT313/20               |                        | 601460       | Beijing Kewei Clinical Diagnostic Reagent Inc.          | COVID-19 Antigen Rapid Test Kit  | N              | 95,0%                      | 0,0%     | 0,0%   | 38,0%   | Ja   |
| AT216/20<br>(AT052/20) |                        | n.a.         | Beijing Lepu Medical Technology Co., Ltd                | SARS-CoV-2 Antigen Rapid Test Kit  | N              | 100,0%                     | 26,1%    | 0,0%   | 46,0%   |  |
| AT820/21               |                        | 00013C       | Beijing O&D Biotech Co., Ltd.                           | Covid-19 Antigen Rapid Test (Colloidal Gold)                                       | N              | 100,0%                     | 75,0%    | 10,0%  | 72,0%   | Ja   |
| AT122/21               |                        | TG1417       | Beijing Tigsun Diagnostics Co.,Ltd.                     | Tigsun COVID-19 Saliva Antigen Rapid Test  | N              | 100,0%                     | 87,0%    | 30,0%  | 80,0%   | Ja   |
| AT022/21               |                        | WJ-2850      | Beijing Wantai Biological Pharmacy Enterprise Co., Ltd. | Wantai SARS-CoV-2 Ag Rapid Test (FIA)  | N              | 100,0%                     | 78,3%    | 0,0%   | 72,0%   |  |
| AT496/20               | AT1265/21              | WJ-2910      | Beijing Wantai Biological Pharmacy Enterprise Co., Ltd. | Wantai SARS-CoV-2 Ag Schnelltest (Kolloidales Gold)                                | N              | 100,0%                     | 25,0%    | 0,0%   | 50,0%   |  |
| AT284/21               |                        | B255C        | Biocan Diagnostics Inc.                                 | Tell Me Fast Rapid Diagnostic Test   | N              | 95,0%                      | 10,0%    | 0,0%   | 42,0%   |  |
| AT787/21               |                        | GMT102       | BioDetect (Xiamen) Biotechnology Co., Ltd               | SARS-Cov-2-Antigen-Schnelltest-Karte   | N              | 95,0%                      | 15,0%    | 0,0%   | 44,0%   | Ja   |
| AT879/21               |                        | 209.01.25.01 | Biohit Healthcare (Hefei) Co., Ltd.                     | SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Method)                              | N              | 100,0%                     | 95,0%    | 20,0%  | 82,0%   | Ja   |
| AT172/21               |                        | 1-367-K020   | BioMaxima S.A.  | SARS-CoV-2 Ag Rapid Test   | N              | 100,0%                     | 60,0%    | 0,0%   | 64,0%   | Ja   |

| AT-Nr.    | AT-Nr.<br>Selbsttest # | Ref-Nr. *    | Hersteller   | Testname   | Zielantigen<br>target antigen | Sensitivität / Sensitivity |          |        |  |  |
|-----------|------------------------|--------------|--|--|-------------------------------|----------------------------|----------|--------|--|--|
|           |                        |              |  |  |                               | Cq ≤25                     | Cq 25-30 | Cq ≥30 | Gesamt-Sensitivität<br>total sensitivity | Omikron<br>Erkennung<br>entsprechend der<br>Bridging Prüfung<br>Omicron detection<br>by bridging |
| AT007/21  |                        | 1509A-I      | BIOMERICA Inc.   | COVID-19-Antigen-Schnelltest (Nasopharyngeal-Abstrich)                         | N                             | 100,0%                     | 30,4%    | 0,0%   | 48,0%                                    | Ja   |
| AT014/20  |                        | RG1901DG     | BIONOTE  | NowCheck® COVID-19 Ag Test   | N                             | 100,0%                     | 65,2%    | 0,0%   | 66,0%                                    | Ja   |
| AT219/20  |                        | COV-201      | BioRepair GmbH   | Covid 19 Antigen Schnelltest   | N                             | 100,0%                     | 78,3%    | 0,0%   | 70,0%                                    |  |
| AT805/21  |                        | n.a.         | Bioscience (Tianjin) Diagnostic Technology Co., Ltd        | Novel Coronavirus(2019-nCoV) Antigen Rapid Test                                | N                             | 100,0%                     | 100,0%   | 60,0%  | 92,0%                                    |  |
| AT025/20  |                        | SW4000605    | BIOSYNEX SWISS SA  | BIOSYNEX COVID-19 Ag BSS   | N                             | 100,0%                     | 78,3%    | 11,1%  | 74,0%                                    | Ja   |
| AT349/21  |                        | 400-678-8982 | BioTeke Corporation (Wuxi) Co.,Ltd.                        | SARS-CoV-2 Antigen Test Kit (Colloidal Gold Method)                            | N                             | 95,0%                      | 10,0%    | 0,0%   | 42,0%                                    | Ja   |
| AT373/20  |                        | COV-19C25    | BTNX, Inc.   | Rapid Response COVID-19 Rapid Test Device                                      | N                             | 94,1%                      | 13,0%    | 10,0%  | 40,0%                                    |  |
| AT924/21  |                        | C2104N01     | Cesna Biyoteknoloji Arastirma Gelistirme Laboratuvar Sist. | Check Up SARS-CoV-2 Nasal Antigen Rapid Test                                   | N                             | 100,0%                     | 45,0%    | 10,0%  | 60,0%                                    | Ja   |
| AT1010/21 |                        | n.a.         | Changzhou Biowin Pharmaceutical Co.,Ltd.                   | Novel Coronavirus(COVID-19) Antigen Test Kit (Colloidal Gold)                  | N                             | 100,0%                     | 35,0%    | 0,0%   | 54,0%                                    | Ja   |
| AT337/20  |                        | CCOV-201     | Chil Tibbi Mal. San. Tic. Ltd. Şti                         | COVID-19 Antigen Schnell Test (Nasopharyngeal / Oropharyngeal Tupfer Kassette) | N                             | 100,0%                     | 60,9%    | 0,0%   | 62,0%                                    | Ja   |
| AT635/21  |                        | n.a.         | Chongqing ISIA BIO-Technology Co.,Ltd                      | ISIA SARS-CoV-2 Antigen Rapid Test Kit   | N                             | 90,0%                      | 15,0%    | 0,0%   | 42,0%                                    |  |
| AT595/21  |                        | n.a.         | Chongqing M&D Biotechnology Co. Ltd.                       | 2019-nCoV Antigen Test Kit   | N                             | 95,0%                      | 25,0%    | 0,0%   | 48,0%                                    |  |
| AT889/21  | AT1350/21              | n.a.         | CITEST Diagnostics Inc.                                    | COVID-19 Antigen Rapid Test (Oral Fluid)                                       | N                             | 100,0%                     | 100,0%   | 90,0%  | 98,0%                                    | Ja   |
| AT409/20  |                        | 7200331      | Co-Innovation Biotech Co. Ltd                              | Whole Power One Step 2019-Novel Coronavirus(2019-nCoV) Antigen Test            | N                             | 100,0%                     | 20,0%    | 0,0%   | 48,0%                                    | Ja   |
| AT498/20  |                        | 1100-5330    | Convergent Technologies                                    | Convergys® COVID-19 Rapid Antigen Test   | N                             | 100,0%                     | 35,0%    | 10,0%  | 56,0%                                    |  |
| AT267/20  |                        | n.a.         | Core Technology Co., Ltd.                                  | Canea COVID-19 Antigen Schnelltest   | N                             | 88,2%                      | 26,1%    | 0,0%   | 42,0%                                    |  |
| AT390/21  |                        | R0182C       | CTK Biotech, Inc.  | OnSite COVID-19 Ag Rapid Test  | N                             | 100,0%                     | 50,0%    | 0,0%   | 60,0%                                    | Ja   |
| AT085/21  |                        | CV19IC       | DNA Diagnostic A/S.  | Covid-19 Antigen Detection Kit   | N                             | 100,0%                     | 39,1%    | 10,0%  | 54,0%                                    |  |
| AT1173/21 | AT1189/21              | 3715270      | Dräger Safety AG & Co. KGaA                                | Dräger Antigen Test SARS-CoV-2   | N                             | 95,0%                      | 10,0%    | 0,0%   | 42,0%                                    | Ja   |
| AT342/21  |                        | DNK-1425-1   | Dynamiker Biotechnology (Tianjin) Co., Ltd.                | Dynamiker SARS-CoV-2 AG Rapid Test   | N                             | 100,0%                     | 100,0%   | 60,0%  | 92,0%                                    | Ja   |

| AT-Nr.    | AT-Nr.<br>Selbsttest # | Ref-Nr. *  | Hersteller  | Testname  | Zielantigen<br>target antigen | Sensitivität / Sensitivity |          |        |        | Gesamt-<br>Sensitivität<br>total<br>sensitivity | Omikron<br>Erkennung<br>entsprechend der<br>Bridging Prüfung<br>Omicron detection<br>by bridging |
|-----------|------------------------|------------|---|---|-------------------------------|----------------------------|----------|--------|--------|---|--|
|           |                        |            |   |   |                               | Cq ≤25                     | Cq 25-30 | Cq ≥30 |        |   |  |
| AT-No.    | AT-No. self-<br>test # | ID-No. *   | Manufacturer  | Test name   |                               |                            |          |        |        |   |  |
| AT032/20  |                        | EGCV0101B  | Edinburgh Genetics Limited  | Edinburgh Genetics ActivXpress+ COVID-19 Antigen Complete Testing Kit | N                             | 100,0%                     | 34,8%    | 0,0%   | 50,0%  |   |  |
| AT491/20  |                        | EBS 1020   | Eurobio Scientific  | EBS SARS-CoV-2 Ag Rapid Test  | N                             | 94,1%                      | 34,8%    | 0,0%   | 48,0%  |   | Ja   |
| AT767/21  |                        | PCSYHN02   | Fosun Diagnostics (Shanghai) Co., Ltd (ehemals Shanghai Fosun Long March Medical Science Co., Ltd.) | Fosun Covid-19 Ag Card  | N                             | 100,0%                     | 20,0%    | 0,0%   | 48,0%  |   | Ja   |
| AT587/21  |                        | 16696722   | FUJIFILM Corporation  | FUJIFILM COVID-19 Ag Test   | N                             | 85,0%                      | 10,0%    | 0,0%   | 38,0%  |   |  |
| AT029/20  |                        | 231906     | Fujirebio Inc.<br>(Mast Diagnostica GmbH)   | ESPLINE® SARS-CoV-2   | N                             | 100,0%                     | 21,7%    | 0,0%   | 46,0%  |   |  |
| AT019/20  |                        | COVAG025   | GenBody Inc.  | GenBody COVID-19 Ag   | N                             | 94,4%                      | 26,1%    | 0,0%   | 46,0%  |   |  |
| AT1100/21 |                        | CoVSLFA-20 | Genobio Pharmaceutical Co., Ltd.  | Virusee® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) (Saliva/Swab) | N                             | 100,0%                     | 95,0%    | 40,0%  | 86,0%  |   |  |
| AT111/20  | AT1200/21              | 52026075   | Genrui Biotech Inc.   | Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold)                   | N                             | 94,1%                      | 56,5%    | 0,0%   | 58,0%  |   | Ja   |
| AT161/20  |                        | P2004      | GenSure Biotech Inc.  | DIA-COVID® COVID-19 Ag Rapid Test Kit                                 | N                             | 94,1%                      | 13,0%    | 0,0%   | 38,0%  |   | Ja   |
| AT166/20  | AT1257/21              | CG2061     | Getein Biotech, Inc.  | One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)                 | N                             | 100,0%                     | 82,6%    | 0,0%   | 72,0%  |   |  |
| AT755/21  |                        | 600008     | Glallergen CO., LTD.  | Novel Corona Virus (2019-nCoV) Ag Rapid Test Kit                      | N                             | 100,0%                     | 100,0%   | 60,0%  | 92,0%  |   |  |
| AT533/21  | AT1295/21              | CG123005   | Goldsite Diagnostics Inc.   | Goldsite COVID-19 SARS-CoV-2 Antigen Kit (Colloidal Gold)             | N                             | 100,0%                     | 35,0%    | 0,0%   | 54,0%  |   | Ja   |
| AT018/20  |                        | n.a.       | Green Cross Medical Science Corp.<br>(Weko Pharma GmbH)   | Genedia W Covid-19 Ag   | N                             | 83,3%                      | 8,7%     | 0,0%   | 34,0%  |   |  |
| AT542/20  |                        | n.a.       | Guangdong Hecin Scientific, Inc.  | 2019-nCoV Antigen Test Kit (colloidal gold method)                    | N                             | 82,4%                      | 13,0%    | 0,0%   | 34,0%  |   | Ja   |
| AT731/21  |                        | LS-C-T-009 | Guangdong Longsee Biomedical Co., Inc.  | Longsee 2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)      | N                             | 100,0%                     | 100,0%   | 100,0% | 100,0% |   | Ja   |
| AT086/20  | AT1158/21              | BE0040     | Guangdong Wesail Biotech Co., Ltd.  | COVID-19 Ag Test Kit  | N                             | 100,0%                     | 52,2%    | 11,1%  | 62,0%  |   | Ja   |
| AT582/21  |                        | n.a.       | Guangzhou Tebsun Bio-Tech Development Co., Ltd.   | Tebsun 2019-nCoV Antigen Test Kit                                     | N                             | 95,0%                      | 65,0%    | 0,0%   | 64,0%  |   |  |
| AT125/20  |                        | W196       | Guangzhou Wondfo Biotech Co. Ltd  | Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)                  | N                             | 88,2%                      | 0,0%     | 0,0%   | 30,0%  |   | Ja   |
| AT276/21  | AT1117/21              | ICOV-802   | Hangzhou AllTest Biotech Co., Ltd.  | Covid-19 Antigen Rapid Test (Oral fluid)                              | N                             | 100,0%                     | 55,0%    | 0,0%   | 62,0%  |   | Ja   |
| AT766/21  | AT1172/21              | INCP-502-N | Hangzhou AllTest Biotech Co., Ltd.  | AllTest SARS-CoV-2 Antigen Rapid Test (Nasal Swab)                    | N                             | 90,0%                      | 20,0%    | 0,0%   | 44,0%  |   | Ja   |

| AT-Nr.    | AT-Nr.<br>Selbsttest # | Ref-Nr. *     | Hersteller  | Testname   | Zielantigen    | Sensitivität / Sensitivity |          |        |  |   |
|-----------|------------------------|---------------|---|--|----------------|----------------------------|----------|--------|--|---|
|           |                        |               |   |  |                | Cq ≤25                     | Cq 25-30 | Cq ≥30 | Gesamt-Sensitivität<br>total sensitivity | Omikron Erkennung<br>entsprechend der Bridging Prüfung<br>Omicron detection by bridging |
| AT-No.    | AT-No. self-test #     | ID-No. *      | Manufacturer  | Test name  | target antigen |                            |          |        |  |   |
| AT568/21  | AT1331/21              | 302281        | Hangzhou Biotest Biotech Co., Ltd                                   | Sienna COVID-19 Antigen-Schnelltestkassette (Nasenabstrich)          | N              | 100,0%                     | 95,0%    | 60,0%  | 90,0%                                    | Ja  |
| AT825/21  |                        | n.a.          | Hangzhou Careomedic Tech Co., Ltd.                                  | SARS-CoV-2-Antigen-Schnelltest                                       | N              | 75,0%                      | 0,0%     | 0,0%   | 30,0%                                    | Ja  |
| AT079/20  |                        | n.a.          | Hangzhou Clongene Biotech Co., Ltd.                                 | Clungene COVID-19 Antigen Rapid Test                                 | N              | 94,4%                      | 34,8%    | 0,0%   | 50,0%                                    | Ja  |
| AT816/21  |                        | n.a.          | Hangzhou DIAN Biotechnology Co., Ltd.                               | GENEDIAN COVID-19 Antigen Test Cassette                              | N              | 90,0%                      | 5,0%     | 0,0%   | 38,0%                                    | Ja  |
| AT415/21  |                        | n.a.          | Hangzhou Funworld Biotech. Co., Ltd                                 | SARS-CoV-2-Antigen-Schnelltestgerät                                  | N              | 100,0%                     | 75,0%    | 0,0%   | 70,0%                                    | Ja  |
| AT818/21  |                        | P211138       | Hangzhou Genesis Biodetection & Biocontrol Co., Ltd.                | KaiBiLi COVID-19 Antigen Pro   | N              | 100,0%                     | 90,0%    | 0,0%   | 76,0%                                    | Ja  |
| AT228/20  |                        | YMC050G       | Hangzhou Immuno Biotech Co.,Ltd.                                    | IMMUNOBIO SARS-CoV-2 Antigen-Schnelltest (COVID-19 Ag)               | N              | 88,2%                      | 13,0%    | 0,0%   | 36,0%                                    | Ja  |
| AT961/21  |                        | n.a.          | Hangzhou Jucheng Medical Products Co., Ltd                          | SARS-CoV-2 Ag Schnelltestkit   | N              | 100,0%                     | 100,0%   | 80,0%  | 96,0%                                    | Ja  |
| AT011/20  | AT1228/21              | n.a.          | Hangzhou Laihe Biotech Co., Ltd. (Lissner Qi GmbH)                  | Lyher Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) | N              | 94,4%                      | 17,4%    | 0,0%   | 42,0%                                    | Ja  |
| AT060/20  |                        | COV-201       | Hangzhou Lysun Biotechnology Co., Ltd.                              | Lysun COVID-19 Antigen Rapid Test Device (Colloidal Gold)            | N              | 100,0%                     | 78,3%    | 0,0%   | 70,0%                                    | Ja  |
| AT628/21  | AT1269/21              | COVG-602      | Hangzhou Sejoy Electronics & Instruments Co.,Ltd.                   | SARS-CoV-2 Antigen Schnelltestkassette                               | N              | 100,0%                     | 50,0%    | 0,0%   | 60,0%                                    | Ja  |
| AT082/20  |                        | n.a.          | Hangzhou Testsea Biotechnology Co., Ltd                             | Testsealabs® Rapid Test Kit COVID-19 Antigen Test Cassette           | N              | 100,0%                     | 47,8%    | 0,0%   | 56,0%                                    | Ja  |
| AT821/21  |                        | IFC-SCoV2-AG  | Hangzhou Zheda Dixun Biological Gene Engineering Co., Ltd.          | SARS-Cov-2 Nucleocapsid(N) Antigen Rapid Test Cassette               | N              | 100,0%                     | 55,0%    | 0,0%   | 62,0%                                    |   |
| AT934/21  |                        | G-C-0104      | Hangzhou Zheda Dixun Biological Gene Engineering Co., Ltd.          | Bisdeal SARS-CoV-2 Antigen-Schnelltest                               | N              | 100,0%                     | 25,0%    | 0,0%   | 50,0%                                    |   |
| AT001/20  | AT1208/21              | GCCOV-502a-H5 | Healgen Scientific Limited Liability Company (Siemens Healthineers) | CLINITEST® Rapid COVID-19 Antigen Test                               | N              | 100,0%                     | 87,0%    | 0,0%   | 76,0%                                    | Ja  |
| AT563/21  |                        | HYT-G01       | Hoyotek Biomedical Co., Ltd.  | Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)          | N              | 90,0%                      | 10,0%    | 0,0%   | 40,0%                                    | Ja  |
| AT1076/21 |                        | n.a.          | Hubei Jinjian Biology Co.,Ltd.                                      | SARS-CoV-2 Antigen Test Kit (Colloidal Gold Method)                  | N              | 100,0%                     | 65,0%    | 0,0%   | 66,0%                                    | Ja  |
| AT083/20  |                        | ACOVA-7025    | Humasis Co., Ltd.   | Humasis COVID-19 Ag Test   | N+S            | 88,2%                      | 21,7%    | 0,0%   | 40,0%                                    |   |
| AT637/21  |                        | BT1389        | Innova Medical Group, Inc.  | INNOVA SARS-CoV-2 Selbsttest (Qualitativer-Antigen-Schnelltest)      | N              | 100,0%                     | 100,0%   | 80,0%  | 96,0%                                    | Ja  |
| AT1073/21 |                        | n.a.          | Innovation Biotech (Beijing) Co. LTD                                | INVBIO One Step Diagnostic Rapid Test Cassette                       | N              | 100,0%                     | 100,0%   | 70,0%  | 94,0%                                    | Ja  |



| AT-Nr.                 | AT-Nr.<br>Selbsttest # | Ref-Nr. *          | Hersteller   | Testname  | Zielantigen    | Sensitivität / Sensitivity |          |        |                     |                                   |
|------------------------|------------------------|--------------------|--|---|----------------|----------------------------|----------|--------|---------------------|-----------------------------------|
|                        |                        |                    |  |   |                | Cq ≤25                     | Cq 25-30 | Cq ≥30 | Gesamt-Sensitivität | Omikron Erkennung                 |
| AT-No.                 | AT-No. self-test #     | ID-No. *           | Manufacturer   | Test name   | target antigen |                            |          |        | total sensitivity   | entsprechend der Bridging Prüfung |
| AT247/21               |                        | n.a.               | Innovation Biotech (Beijing) Co.,Ltd                               | INVBIO Antigen Rapid Test Device (Saliva)   | N              | 95,0%                      | 25,0%    | 0,0%   | 48,0%               | Ja                                |
| AT199/21               |                        | n.a.               | Innovita (Tangshan) Biological Technology Co.; LTD.                | 2019-nCoV Ag Test (Latex Chromatography Assay)  | N              | 85,0%                      | 5,0%     | 0,0%   | 36,0%               | Ja                                |
| AT981/21<br>(AT574/21) |                        | ITP16010-TC25      | InTec Products, Inc.   | Rapid SARS-CoV-2 Antigen Test Colloidal Gold (Nasopharyngeal/Nasal specimen)                                | N              | 100,0%                     | 95,0%    | 30,0%  | 84,0%               | Ja                                |
| AT849/21               |                        | n.a.               | Jiangsu Biopertectus Technologies Co., Ltd.                        | Novel Coronavirus (SARS-CoV-2) Ag Rapid Test Kit  | N              | 100,0%                     | 75,0%    | 0,0%   | 70,0%               | Ja                                |
| AT418/20               |                        | n.a.               | Jiangsu Diagnostics Biotechnology Co., Ltd                         | COVID-19 Antigen Rapid Test Cassette (Colloidal Gold)   | N              | 100,0%                     | 78,3%    | 0,0%   | 68,0%               | Ja                                |
| AT231/20               |                        | n.a.               | Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd        | Konsung COVID-19 Antigen Rapid Test Kit   | N              | 100,0%                     | 70,0%    | 30,0%  | 74,0%               | Ja                                |
| AT244/20               | AT1298/21              | 1031-02            | Jiangsu Medomics Medical Technology Co., Ltd                       | SARS-CoV-2-Antigen-Testkit (LFIA)   | N              | 94,1%                      | 21,7%    | 0,0%   | 42,0%               | Ja                                |
| AT1082/21              |                        | R220T001B0C0       | Jiangsu Mole Bioscience Co., Ltd                                   | SARS-CoV-2 Antigen Test Cassette  | N              | 100,0%                     | 65,0%    | 0,0%   | 66,0%               | Ja                                |
| AT883/21               |                        | CO-05              | Jiangsu Well Biotech Co., Ltd.                                     | COVID-19 Schnelltestgerät   | N              | 100,0%                     | 95,0%    | 40,0%  | 86,0%               | Ja                                |
| AT770/21               |                        | n.a.               | Jiangxi Province JinHuan Medical Instrument Co.,LTD.               | COVID-19 antigen Schnelltest (Kolloidales Gold) / Novel Coronavirus(SARS-CoV-2) Antigen Rapid Detection Kit | N              | 100,0%                     | 95,0%    | 60,0%  | 90,0%               | Ja                                |
| AT882/21               |                        | n.a.               | Jiaxing Wisetest Bio-Tech Co., Ltd.                                | Saliva SARS-CoV-2 (2019-nCoV) Antigen Test Kit (Nanocarbon Assay)   | N              | 85,0%                      | 15,0%    | 10,0%  | 42,0%               | Ja                                |
| AT559/21               |                        | n.a.               | Jinan Babio Biotechnology Co., Ltd.                                | SARS-CoV-2 Antigen Rapid Detection Kit (Colloidal Gold Method)  | N              | 100,0%                     | 35,0%    | 0,0%   | 54,0%               | Ja                                |
| AT236/20               | AT1276/21              | n.a.               | Joinstar Biomedical Technology Co., Ltd (CIV care impuls Vertrieb) | COVID-19 Antigen Schnelltest (Colloidal Gold)   | N              | 100,0%                     | 60,9%    | 0,0%   | 64,0%               | Ja                                |
| AT527/20               |                        | COV-AG-20 / G10313 | JOYSBIO (Tianjin) Biotechnology Co., Ltd.                          | SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) SPUCKTEST  | N              | 100,0%                     | 90,0%    | 0,0%   | 76,0%               | Ja                                |
| AT692/21               |                        | G10322             | JOYSBIO (Tianjin) Biotechnology Co.,Ltd.                           | Joysbio SARS-CoV-2 Antigen rapid test kit -PRO (Colloidal Gold)   | N              | 100,0%                     | 35,0%    | 0,0%   | 54,0%               | Ja                                |
| AT1287/21              |                        | NCV11              | Koch Biotechnology (Beijing) Co., Ltd.                             | COVID-19 Antigen Rapid Test Kit   | N              | 100,0%                     | 100,0%   | 40,0%  | 88,0%               | Ja                                |
| AT127/20               | AT1284/21 / AT1155/21  | B63000             | Labnovation Technologies, Inc.                                     | Labnovation SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)  | N              | 94,1%                      | 17,4%    | 0,0%   | 40,0%               | Ja                                |
| AT1054/21              |                        | n.a.               | Lifecosc Biotech Limited   | COVID-19 Rapid Test Cassette Antigen Test Kit   | N              | 100,0%                     | 100,0%   | 100,0% | 100,0%              | Ja                                |
| AT455/20               |                        | PR210101           | Lumigenex (Suzhou) Co., Ltd.                                       | PocRoc SARS-CoV-2, Antigen Schnelltest Set (Kolloidales Gold)   | N              | 100,0%                     | 65,2%    | 0,0%   | 64,0%               | Ja                                |
| AT151/20               |                        | 71110              | LumiQuick Diagnostics, Inc.  | Quick Profile Covid-19 Antigen Test Card  | N              | 100,0%                     | 91,3%    | 20,0%  | 80,0%               | Ja                                |



| AT-Nr.   | AT-Nr.<br>Selbsttest # | Ref-Nr. *                     | Hersteller                                     | Testname   | Zielantigen    | Sensitivität / Sensitivity |          |        |  |   |
|----------|------------------------|-------------------------------|--|--|----------------|----------------------------|----------|--------|--|---|
|          |                        |                               |  |  |                | Cq ≤25                     | Cq 25-30 | Cq ≥30 | Gesamt-Sensitivität<br>total sensitivity | Omikron Erkennung<br>entsprechend der Bridging Prüfung<br>Omicron detection by bridging |
| AT-No.   | AT-No. self-test #     | ID-No. *                      | Manufacturer                                   | Test name  | target antigen |                            |          |        |  |   |
| AT075/20 |                        | SPEC-32312 R2<br>ART-00571 R4 | LumiraDX                                       | LumiraDx SARS-CoV-2 Ag Test  | N              | 100,0%                     | 52,2%    | 0,0%   | 60,0%                                    | Ja  |
| AT012/20 |                        | 76748                         | MEDsan GmbH                                    | MEDsan® SARS-CoV-2 Antigen Rapid Test  | N              | 100,0%                     | 47,8%    | 0,0%   | 58,0%                                    | Ja  |
| AT214/20 |                        | CP01810011                    | Merlin Biomedical (Xiamen) Co., Ltd.           | SARS-CoV-2 Antigen Rapid Test Cassette   | N              | 100,0%                     | 82,6%    | 0,0%   | 72,0%                                    | Ja  |
| AT790/21 |                        | CP02150011                    | Merlin Biomedical (Xiamen) Co., Ltd.           | SARS-CoV-2 Antigen Rapid Test Cassette   | N              | 100,0%                     | 55,0%    | 0,0%   | 62,0%                                    |   |
| AT500/21 | AT1280/21              | 3011035                       | Mexacare COVID-19 Antigen Schnelltest          | Mexacare GmbH  | N              | 100,0%                     | 80,0%    | 10,0%  | 74,0%                                    | Ja  |
| AT047/20 |                        | 0230005SP                     | Mölab GmbH                                     | mö-screen Corona Antigen Test  | N              | 100,0%                     | 47,8%    | 0,0%   | 58,0%                                    | Ja  |
| AT198/20 |                        | 07AG6020B                     | MP Biomedicals Germany GmbH                    | Rapid SARS-CoV-2 Antigen Test Card   | N              | 100,0%                     | 43,5%    | 0,0%   | 54,0%                                    | Ja  |
| AT823/21 | AT1281/21              | 0000000168                    | MSP bodmann GmbH                               | MSP SARS-CoV-2 Antigen-Schnelltest   | N              | 100,0%                     | 20,0%    | 0,0%   | 48,0%                                    | Ja  |
| AT021/20 | AT1293/21              | 243103N-20                    | nal von minden gmbh                            | NADAL® COVID-19 Ag Schnelltest   | N              | 83,3%                      | 13,0%    | 0,0%   | 36,0%                                    | Ja  |
| AT593/21 |                        | 500200                        | Nanjing Liming Bio-Products Co., Ltd.          | StrongStep® SARS-COV2 Antigen Rapid Test   | N              | 95,0%                      | 80,0%    | 0,0%   | 70,0%                                    | Ja  |
| AT462/20 |                        | n.a.                          | Nanjing Norman Biological Technology Co., Ltd  | Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)                           | N              | 94,1%                      | 26,1%    | 0,0%   | 44,0%                                    | Ja  |
| AT678/21 |                        | RQ005                         | Nanjing Synthgene Medical Technology Co., Ltd. | Synthgene Neues Coronavirus (SARS-CoV-2) Antigen-Schnellerkennungskit (Collate Gold-Methode) | N              | 100,0%                     | 35,0%    | 0,0%   | 54,0%                                    | Ja  |
| AT255/20 |                        | C8602C                        | Nanjing Vazyme Medical Technology Co., Ltd.    | Vazyme SARS-CoV-2 Antigen Detection Kit (Colloidal Gold-Based)                               | N+S            | 85,0%                      | 5,0%     | 0,0%   | 36,0%                                    | Ja  |
| AT090/20 |                        | FRC0G 020P                    | NanoEntek Inc                                  | FREND™ COVID-19 Ag   | N              | 88,2%                      | 8,7%     | 0,0%   | 34,0%                                    | Ja  |
| AT517/20 |                        | 17252668                      | Nantong Diagnos Biotechnology Co., Ltd.        | COVID-19 Antigen Saliva Test Kit (Colloidal Gold)  | N              | 100,0%                     | 56,5%    | 0,0%   | 60,0%                                    | Ja  |
| AT425/21 |                        | n.a.                          | Nantong Egens Biotechnology                    | SARS-CoV-2 Antigen Rapid Test  | N              | 100,0%                     | 100,0%   | 50,0%  | 90,0%                                    | Ja  |
| AT722/21 |                        | SVRAG                         | Neo-nostics (Suzhou) Bioengineering Co., Ltd.  | COVID 19 Antigen Test Kit (Colloidal Gold Method)  | N              | 100,0%                     | 75,0%    | 10,0%  | 72,0%                                    | Ja  |
| AT331/21 | AT1210/21              | COVID-19-NG08                 | New Gene (Hangzhou) Bioengineering Co., Ltd.   | Covid-19-Antigen-Testkit   | N              | 100,0%                     | 87,0%    | 20,0%  | 78,0%                                    | Ja  |
| AT989/21 |                        | NBMLRS-XG-S2                  | Ningbo Beautiful Life Medical Biotechnology    | Saliva SARS-CoV-2(2019-nCoV) Antigen Test Kit (Nanocarbon Assay)                             | N              | 100,0%                     | 35,0%    | 0,0%   | 54,0%                                    |   |
| AT036/21 | AT034/22               | MY28                          | Novatech Tibbi Cihaz Ürünleri San. Ve Tic.A.S. | novacheck®-Ag SARS-CoV-2 Covid-19 Antigen Rapid Test   | N              | 94,1%                      | 21,7%    | 0,0%   | 42,0%                                    |   |
| AT117/20 |                        | CAT-01                        | Oncosem Onkolojik Sistemler San. Ve Tic.A.S.   | CAT Antigen Covid Rapid Test   | N              | 94,1%                      | 30,4%    | 0,0%   | 46,0%                                    |   |

| AT-Nr.              | AT-Nr.<br>Selbsttest # | Ref-Nr. *                  | Hersteller  | Testname   | Zielantigen    | Sensitivität / Sensitivity |          |        |  |   |
|---------------------|------------------------|----------------------------|---|--|----------------|----------------------------|----------|--------|--|---|
|                     |                        |                            |   |  |                | Cq ≤25                     | Cq 25-30 | Cq ≥30 | Gesamt-Sensitivität<br>total sensitivity | Omikron Erkennung<br>entsprechend der Bridging Prüfung<br>Omicron detection by bridging |
| AT-No.              | AT-No. self-test #     | ID-No. *                   | Manufacturer  | Test name  | target antigen |                            |          |        |  |   |
| AT538/20            |                        | COV04S                     | PCL, Inc.   | PCL COVID19 Ag Gold Saliva   | N              | 100,0%                     | 52,2%    | 0,0%   | 58,0%                                    | Ja  |
| AT209/20            | AT002/22               | n.a.                       | PerGrande BioTech Development Co., Ltd.                 | SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Immunochromatographic Assay)  | N+S            | 100,0%                     | 17,4%    | 0,0%   | 42,0%                                    | Ja  |
| AT078/20            |                        | PR-FC13                    | Precision Biosensor Inc. (Axon Lab AG)                  | Exdia COVID-19-Ag-Test   | N              | 100,0%                     | 60,9%    | 0,0%   | 64,0%                                    | Ja  |
| AT376/20            |                        | V1330                      | ProGnosis Biotech                                       | Rapid Test Ag 2019-nCoV  | N              | 94,1%                      | 65,2%    | 10,0%  | 64,0%                                    | Ja  |
| AT863/21            |                        | n.a.                       | Pro-med (Beijing) Technology Co., Ltd.                  | Pro-med COVID-19 Antigen Rapid Detection Kit                                   | N              | 80,0%                      | 5,0%     | 0,0%   | 34,0%                                    |   |
| AT935/21            |                        | n.a.                       | Qingdao AIBO Diagnostic CO., Ltd.                       | Novel Coronavirus (COVID-19) Antigen Rapid Test Kit                            | N              | 100,0%                     | 20,0%    | 0,0%   | 48,0%                                    | Ja  |
| AT320/20            | AT1224/21              | H100G                      | Qingdao Hightop Biotech Co., Ltd.                       | Hightop SARS-CoV-2 (Covid-19) Antigen Rapid Test                               | N              | 100,0%                     | 43,5%    | 0,0%   | 54,0%                                    | Ja  |
| AT008/20            |                        | N6803                      | R-Biopharm AG   | RIDA@QUICK SARS-CoV-2 Antigen  | N              | 100,0%                     | 17,4%    | 0,0%   | 44,0%                                    |   |
| AT199/20            |                        | COV Ag-6012                | Safecare Biotech Hangzhou Co., Ltd.                     | Safecare COVID-19 Ag Rapid Test Kit (Swab)                                     | N              | 100,0%                     | 60,9%    | 0,0%   | 62,0%                                    | Ja  |
| AT106/20            |                        | COV-06-S                   | Salofa OY   | salocor SARS-CoV-2 Antigen Rapid Test Cassette (Nasopharyngeal swab)           | N              | 82,4%                      | 13,0%    | 0,0%   | 34,0%                                    | Ja  |
| AT506/21            |                        | S3109E                     | Sansure Biotech Inc.                                    | SARS-CoV-2 Rapid Antigen Test (Colloidal Gold Method)                          | N              | 100,0%                     | 25,0%    | 0,0%   | 50,0%                                    | Ja  |
| AT069/20            |                        | 34                         | ScheBo Biotech AG                                       | ScheBo SARS-CoV-2 Quick Antigen  | N              | 100,0%                     | 91,3%    | 10,0%  | 78,0%                                    | Ja  |
| AT023/20 (AT004/20) | AT1154/21              | Q-NCOV-01G (9901-NCOV-01G) | SD Biosensor, Inc. (Roche Diagnostics GmbH)             | STANDARD Q COVID-19 Ag Test (SARS-CoV-2 Rapid Antigen Test)                    | N              | 88,9%                      | 30,4%    | 0,0%   | 46,0%                                    | Ja  |
| AT022/20            |                        | F-NCOV-01G                 | SD Biosensor, Inc.                                      | STANDARD F COVID-19 Ag FIA   | N              | 100,0%                     | 65,2%    | 0,0%   | 66,0%                                    | Ja  |
| AT1064/21           |                        | 2.13.1.587                 | Senova Gesellschaft für Biowissenschaft und Technik mbH | GreenLight SARS-CoV-2 Antigen-Test   | N              | 95,0%                      | 10,0%    | 0,0%   | 42,0%                                    |   |
| AT918/21            | AT1291/21 / AT1338/21  | SCVC02                     | SGA Mühendislik DAN. EG. İcve DIS.Ltd.STİ               | V-Chek SARS-CoV-2 Rapid Ag Test Kit (Colloidal Gold)                           | N              | 94,1%                      | 26,1%    | 0,0%   | 44,0%                                    | Ja  |
| AT748/21            |                        | n.a.                       | Shanghai Liangrun Biomedicine Technology Co., Ltd.      | LionRun™ SARS-CoV-2 Antigen Rapid Test Kit (Lateral Flow Immunoassay)          | N              | 100,0%                     | 85,0%    | 0,0%   | 74,0%                                    | Ja  |
| AT857/21            |                        | n.a.                       | Shen Zhen Zi Jian Biotechnology Co., Ltd.               | Zijian SARS-CoV-2 (COVID-19) Antigen Rapid Detection Kit (Lateral Flow Method) | N              | 80,0%                      | 10,0%    | 0,0%   | 36,0%                                    | Ja  |
| AT928/21            |                        | CG201A                     | Shenzhen CAS-Envision Medical Technology Co., Ltd.      | SARS-Cov-2 Antigen Rapid Detection Kit   | N              | 100,0%                     | 100,0%   | 70,0%  | 94,0%                                    | Ja  |
| AT260/21            |                        | n.a.                       | Shenzhen Dymind Biotechnology Co., Ltd.                 | SARS-CoV-2 Antigen Test Kit (Colloidal Gold)                                   | N              | 100,0%                     | 30,0%    | 0,0%   | 52,0%                                    |   |

| AT-Nr.    | AT-Nr.<br>Selbsttest # | Ref-Nr. *              | Hersteller  | Testname   | Zielantigen    | Sensitivität / Sensitivity |          |        |   | Omikron<br>Erkennung<br>entsprechend der<br>Bridging Prüfung |
|-----------|------------------------|------------------------|---|--|----------------|----------------------------|----------|--------|---|--|
|           |                        |                        |   |  |                | Cq ≤25                     | Cq 25-30 | Cq ≥30 | Gesamt-<br>Sensitivität<br>total<br>sensitivity |  |
| AT-No.    | AT-No. self-<br>test # | ID-No. *               | Manufacturer  | Test name  | target antigen |                            |          |        |   | Omicron detection<br>by bridging                             |
| AT829/21  |                        | n.a.                   | Shenzhen Dymind Biotechnology Co., Ltd.             | SARS-CoV-2 Antigen Test Kit (Colloidal Gold)   | N              | 100,0%                     | 30,0%    | 0,0%   | 52,0%   |  |
| AT458/21  |                        | HRK-6820               | Shenzhen Huaree Technology Co., Ltd.                | SARS-CoV-2 Antigen Saliva Rapid Test Kit   | N              | 100,0%                     | 90,0%    | 10,0%  | 78,0%   |  |
| AT424/21  |                        | HRK-6620               | Shenzhen Huaree Technology Co., Ltd.                | SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)   | N              | 100,0%                     | 45,0%    | 0,0%   | 58,0%   |  |
| AT472/21  |                        | 203-020                | Shenzhen Huian Biosci Technology Co., Ltd.          | SARS-CoV-2 Antigen Test Kit (Colloidal Gold)   | N              | 100,0%                     | 60,0%    | 0,0%   | 64,0%   | Ja   |
| AT1065/21 |                        | 808151-1               | Shenzhen Kang Sheng Bao Bio- Technology Co., Ltd.   | SARS-CoV-2 Antigen Rapid Test (Lateral Flow Assay)   | N              | 95,0%                      | 10,0%    | 0,0%   | 42,0%   | Ja   |
| AT1019/21 |                        | 150129                 | Shenzhen Kingfocus Biomedical Engineering Co., Ltd. | COVID-19 Antigen Detection Kit (Quantum Dots-Based Immunofluorescence Chromatography)              | N              | 100,0%                     | 95,0%    | 60,0%  | 90,0%   | Ja   |
| AT420/21  |                        | K602-20                | Shenzhen Kisshealth Biotechnology Co., Ltd.         | KISSH SARS-CoV-2 Antigen Test Kit (GICA)   | N              | 100,0%                     | 85,0%    | 10,0%  | 76,0%   |  |
| AT417/20  |                        | n.a.                   | Shenzhen Lvshiyuan Biotechnology Co., Ltd.          | Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)                                    | N              | 100,0%                     | 95,7%    | 40,0%  | 86,0%   |  |
| AT070/20  |                        | MF-60                  | Shenzhen Microprofit Biotech Co., Ltd.              | fluorecare COVID-19 SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay) | S              | 100,0%                     | 47,8%    | 10,0%  | 58,0%   |  |
| AT071/20  |                        | MF-63                  | Shenzhen Microprofit Biotech Co., Ltd.              | SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay)                                       | S              | 100,0%                     | 85,0%    | 10,0%  | 76,0%   |  |
| AT544/21  | AT1308/21              | MF-68                  | Shenzhen Microprofit Biotech Co., Ltd.              | fluorecare SARS-CoV-2 Antigen Test Kit   | N              | 90,0%                      | 15,0%    | 0,0%   | 42,0%   | Ja   |
| AT844/21  |                        | RNS92048B              | Shenzhen Reagent Technology Co., Ltd.               | SARS-CoV-2 Antigen IVD kit SWAB  | N+S            | 100,0%                     | 50,0%    | 0,0%   | 60,0%   | Ja   |
| AT108/20  | AT004/22               | LFA0401-25N            | Shenzhen Watmind Medical Co., Ltd.                  | SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)   | N              | 100,0%                     | 95,7%    | 20,0%  | 82,0%   | Ja   |
| AT385/20  |                        | LFB0401-25N            | Shenzhen Watmind Medical Co., Ltd.                  | SARS-CoV-2 Ag Diagnostic Test Kit (Immunofluorescence)   | N              | 100,0%                     | 60,9%    | 0,0%   | 62,0%   | Ja   |
| AT409/21  |                        | G86247                 | Shenzhen YHLO Biotech Co., Ltd.                     | GLINE-2019-nCoV Ag   | N              | 90,0%                      | 30,0%    | 0,0%   | 48,0%   | Ja   |
| AT211/20  |                        | n.a.                   | Shenzhen Zhenrui Biotech Co., Ltd.                  | Zhenrui COVID-19 (SARS-COV-2) Antigen Test Kits  | N              | 82,4%                      | 13,0%    | 0,0%   | 34,0%   |  |
| AT941/21  |                        | T3701W, T3702W, T3706W | Sichuan Xincheng Biological Co., Ltd.               | SARS-CoV-2 Antigen Assay Kit by Latex Immunochromatography method                                  | N              | 100,0%                     | 95,0%    | 40,0%  | 86,0%   |  |
| AT837/21  |                        | SP-SW 106              | Spring Healthcare Services Sp zoo                   | SARS-CoV-2 Antigen Schnelltestkassette (Abstrich)  | N              | 100,0%                     | 70,0%    | 0,0%   | 68,0%   | Ja   |
| AT010/20  |                        | CAGT025E0              | Sugentech, Inc.                                     | SGTi-flex COVID-19 Ag  | N              | 100,0%                     | 73,9%    | 0,0%   | 68,0%   | Ja   |
| AT789/21  |                        | COVID19AGVCG           | SureScreen Diagnostics Ltd.                         | COVID-19 Antigen Rapid Test Cassette (Nasal Swab)  | N              | 100,0%                     | 20,0%    | 0,0%   | 48,0%   |  |

| AT-Nr.    | AT-Nr.<br>Selbsttest # | Ref-Nr. * | Hersteller   | Testname  | Zielantigen    | Sensitivität / Sensitivity |          |        |  |   |
|-----------|------------------------|-----------|--|---|----------------|----------------------------|----------|--------|--|---|
|           |                        |           |  |   |                | Cq ≤25                     | Cq 25-30 | Cq ≥30 | Gesamt-Sensitivität<br>total sensitivity | Omikron Erkennung<br>entsprechend der Bridging Prüfung<br>Omicron detection by bridging |
| AT-No.    | AT-No. self-test #     | ID-No. *  | Manufacturer   | Test name   | target antigen |                            |          |        |  |   |
| AT765/21  |                        | n.a.      | Surge Medical Inc.                                       | COVID-19 Antigen Test Kit                               | N              | 100,0%                     | 40,0%    | 0,0%   | 56,0%                                    | Ja  |
| AT830/21  |                        | n.a.      | Suzhou Soochow University Saier Immuno Biotech Co., Ltd. | InstantSure Covid-19 Ag CARD                            | N              | 100,0%                     | 100,0%   | 80,0%  | 96,0%                                    | Ja  |
| AT848/21  |                        | 04A024    | TBG Biotechnology Xiamen Inc.                            | TBG SARS-CoV-2 Antigen Rapid Test                       | N              | 95,0%                      | 80,0%    | 10,0%  | 72,0%                                    |   |
| AT379/20  |                        | 2276-20   | Toda Pharma  | Toda Coronadiag Ag                                      | N              | 100,0%                     | 95,7%    | 40,0%  | 86,0%                                    |   |
| AT044/21  |                        | C011906   | Triplex International Biosciences (China) Co., Ltd.      | SARS-CoV-2 Antigen Rapid Test Kit                       | N              | 100,0%                     | 87,0%    | 20,0%  | 78,0%                                    |   |
| AT492/20  | AT1222/21              | RTC03     | Türklab Tibbi Malzemeleri San. Ve Tic. A.S               | Rapidan Tester COVID-19 Ag Test                         | N              | 90,0%                      | 10,0%    | 0,0%   | 40,0%                                    | Ja  |
| AT075/21  |                        | 012G521   | ulti med Products (Deutschland) GmbH                     | COVID-19 Antigen Speicheltest (Immunochromatographie)   | N              | 100,0%                     | 95,7%    | 20,0%  | 82,0%                                    | Ja  |
| AT507/20  |                        | VSCD02    | Vitrosens Biyoteknoloji Ltd. Sti                         | RapidFor SARS-CoV-2 Rapid Antigen Test Colloidal Gold   | N              | 100,0%                     | 30,4%    | 0,0%   | 48,0%                                    | Ja  |
| AT711/21  |                        | n.a.      | Weihai Kangzhou Biotechnology Engineering Co., Ltd.      | Kanzone COVID-19 Antigen Rapid Test                     | N              | 90,0%                      | 5,0%     | 0,0%   | 38,0%                                    |   |
| AT1160/21 |                        | COVA1     | Willi Fox GmbH   | Willi Fox - COVID-19 Antigen Test                       | N              | 100,0%                     | 45,0%    | 0,0%   | 58,0%                                    | Ja  |
| AT430/20  | AT1289/21              | W-Ag03-20 | Wuhan EasyDiagnosis Biomedicine Co., Ltd.                | COVID-19 (SARS-CoV-2) Antigen Test Kit                  | N              | 100,0%                     | 73,9%    | 0,0%   | 68,0%                                    | Ja  |
| AT997/21  |                        | FP-318    | Wuhan HealthCare Biotechnology Co., Ltd.                 | SARS-CoV-2 Antigen Test Kit (Colloidal Gold)            | N              | 90,0%                      | 0,0%     | 0,0%   | 36,0%                                    | Ja  |
| AT172/20  |                        | SF24025   | Wuhan Life Origin Biotech Joint Stock Co., Ltd.          | SARS-CoV-2 Antigen Assay Kit (Immunochromatography)     | n.a.           | 100,0%                     | 56,5%    | 0,0%   | 60,0%                                    |   |
| AT429/20  |                        | CoV2Ag-25 | Wuhan UNscience Biotechnology Co., Ltd.                  | SARS-CoV-2 Antigen Rapid Test Kit                       | N              | 88,2%                      | 17,4%    | 0,0%   | 38,0%                                    |   |
| AT847/21  |                        | COV-S31   | Wuxi Biohermes Bio & Medical Technology Co., Ltd.        | SARS-CoV-2 Antigen Test Kit (Lateral Flow Assay)        | N              | 100,0%                     | 60,0%    | 0,0%   | 64,0%                                    | Ja  |
| AT246/21  | AT1279/21              | CG01Ag-25 | Xiamen AmonMed Biotechnology Co., Ltd.                   | COVID-19 Antigen Rapid Test Kit (Colloidal Gold)        | N              | 100,0%                     | 87,0%    | 30,0%  | 80,0%                                    | Ja  |
| AT116/20  | AT1165/21              | 07AG6020B | Xiamen Boson Biotech Co., Ltd.                           | SARS-CoV-2 Antigen Schnelltest                          | N              | 100,0%                     | 43,5%    | 0,0%   | 54,0%                                    | Ja  |
| AT109/20  | AT1297/21              | 51232012  | Xiamen WIZ Biotech Co., Ltd.                             | Wizbiotech SARS-CoV-2 Antigen Rapid Test                | N              | 88,2%                      | 13,0%    | 0,0%   | 36,0%                                    | Ja  |
| AT311/21  |                        | n.a.      | ZandCell AB  | ZandCell COVID-19 Saliva Antigen-Test                   | N              | 90,0%                      | 5,0%     | 0,0%   | 38,0%                                    |   |
| AT167/20  |                        | n.a.      | Zet Medikal Tekstil Dis Ticaret Ltd. STI.                | softec SARS COV-2 (Covid-19) Antigen Test Kit           | N              | 82,4%                      | 21,7%    | 10,0%  | 40,0%                                    |   |
| AT102/20  |                        | COVG10S   | Zhejiang Anji Saianfu Biotech Co.,Ltd.                   | reOpenTest COVID-19 Antigen Rapid Test (Colloidal Gold) | N              | 94,1%                      | 30,4%    | 0,0%   | 46,0%                                    | Ja  |

| AT-Nr.   | AT-Nr.<br>Selbsttest # | Ref-Nr. *  | Hersteller                                  | Testname  | Zielantigen    | Sensitivität / Sensitivity |          |        |  |   |
|----------|------------------------|------------|---|---|----------------|----------------------------|----------|--------|--|---|
|          |                        |            |   |   |                | Cq ≤25                     | Cq 25-30 | Cq ≥30 | Gesamt-Sensitivität<br>total sensitivity | Omikron Erkennung<br>entsprechend der Bridging Prüfung<br>Omicron detection by bridging |
| AT-No.   | AT-No. self-test #     | ID-No. *   | Manufacturer                                | Test name   | target antigen |                            |          |        |  |   |
| AT516/21 |                        | n.a.       | Zhejiang Gene Science Co., Ltd.             | Novel Coronavirus (COVID-19) Antigen Detection Kit (Latex Immunochromatography)               | N              | 100,0%                     | 70,0%    | 40,0%  | 76,0%                                    |   |
| AT108/22 |                        | GCCOV-502a | Zhejiang Orient Gene Biotech Co.,Ltd        | Coronavirus Ag Rapid Test Cassette (Swab)   | N              | 100,0%                     | 87,0%    | 0,0%   | 76,0%                                    | Ja  |
| AT839/21 |                        | n.a.       | Zhongxiu Science and Technology Co., Ltd    | Neuartiges Coronavirus (2019-nCoV) Antigendetektionsreagenz (immunochromatographischer Assay) | N              | 100,0%                     | 70,0%    | 10,0%  | 70,0%                                    | Ja  |
| AT583/21 |                        | RDC-802    | Zhuhai Encode Medical Engineering Co., Ltd. | ENCODE SARS-COV-2 Antigen Rapid Test Device   | N              | 95,0%                      | 15,0%    | 0,0%   | 44,0%                                    | Ja  |
| AT542/21 | AT1290/21              | n.a.       | Zhuhai Lituo Biotechnology Co., Ltd.        | COVID-19 Antigen Detection Kit (Colloidal Gold)   | N              | 100,0%                     | 80,0%    | 0,0%   | 72,0%                                    |   |

**Abkürzungen und Zeichenerklärung / Abbreviations and explanation of symbols:**

Cq = Quantifizierungszyklus / quantitative cycle

n.a. = nicht verfügbar / not available

# = Korrespondierende baugleiche Selbsttests (wurden jedoch nicht zusätzlich evaluiert). / Corresponding self-tests of identical design (but were not additionally evaluated).

\* Ref-Nr. oder Katalog-Nummer wie bei Einreichung zur Evaluierung / Ref. No. or catalog number as submitted for evaluation

N = Nukleocapsid Protein / nucleocapsid protein

S = Spike Protein / spike protein

**Die Liste dient der Information und erhebt keinen Anspruch auf Vollständigkeit. Änderungen bleiben vorbehalten.**

**The list is for information only and does not claim to be complete. Subject to change without notice.**

**Tabelle 2: Ergebnisse der SARS-CoV-2 Antigenschnelltests, die das Sensitivitätskriterium nicht erfüllen**

Hinweis: Alle hier gelisteten Tests wurden von der BfArM Liste gestrichen, diese Produkte sind auf dem Markt ggf. auch nicht mehr erhältlich. Tests, die in grau dargestellt sind, werden in dieser Zusammensetzung nicht mehr hergestellt und sind daher auf dem Markt nicht verfügbar.

**Table 2: SARS-CoV-2 antigen rapid diagnostic tests missing the sensitivity criteria**

Note: All tests listed here have been removed from the BfArM list, these products may no longer be available on the market. Tests shown in gray are no longer manufactured in this composition and are therefore not available on the market.

| AT-Nr. /<br>AT-No. | Ref-Nr./<br>ID-No. *     | Hersteller /<br>Manufacturer                      | Testname /<br>Test name   | Zielantigen /<br>target antigen | Sensitivität / Sensitivity |          |        |   |
|--------------------|--------------------------|---|---|---------------------------------|----------------------------|----------|--------|---|
|                    |                          |   |   |                                 | Cq ≤25                     | Cq 25-30 | Cq ≥30 | Gesamt-<br>Sensitivität /<br>total<br>sensitivity |
| AT506/20           | ABCAR-020                | Absology Co.,Ltd.                                 | INIST COVID-19 Ag Rapid   | N                               | 0,0%                       | 0,0%     | 0,0%   | 0,0%  |
| AT054/20           | INCP-ACO502              | Acro Biotech, Inc.                                | Acro COVID-19 Antigen Rapid Test  | n.a.                            | 16,7%                      | 0,0%     | 0,0%   | 6,0%  |
| AT469/20           | AKBR4019020              | Aikang Diagnostics Co., Ltd.                      | SARS-CoV-2 Antigen Test Kit (Immunochromatography)                                      | N                               | 11,8%                      | 0,0%     | 0,0%   | 4,0%  |
| AT163/20           | MPV: M30020-01 / -<br>02 | Beijing Savant Biotechnology Co., Ltd.            | New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunchromatography) | N                               | 0,0%                       | 0,0%     | 0,0%   | 0,0%  |
| AT586/21           | RAPG-CVA-019             | Biopanda Reagents                                 | COVID-19 Antigen-Schnelltest  | N                               | 60,0%                      | 0,0%     | 0,0%   | 24,0%   |
| AT051/20           | SC820001PC               | CerTest Biotec S. L.                              | CerTest Biotec SARS-CoV-2 Ag Test   | N                               | 29,4%                      | 0,0%     | 0,0%   | 10,0%   |
| AT543/21           | n.a.                     | Changsha Sanji Bio-technology Co., Ltd            | SARS-CoV-2 Antigen Rapid Test (Lateral Flow Method)                                     | N                               | 20,0%                      | 0,0%     | 0,0%   | 8,0%  |
| AT048/20           | C-1023                   | Coris BioConcept                                  | COVID-19 Ag Respi-Strip   | N                               | 33,3%                      | 0,0%     | 0,0%   | 12,0%   |
| AT715/21           | DCOV-201                 | Dejavu Medikal San. Ve Tic. Ltd. Sti.             | COVID-19 Antigen Schnelltest  | N                               | 70,0%                      | 0,0%     | 0,0%   | 28,0%   |
| AT573/21           | S03#                     | Diasia Biomedical Technology Co., Ltd.            | DIASIA SARS-CoV-2 Antigen Rapid Test Kit  | N                               | 55,0%                      | 0,0%     | 0,0%   | 22,0%   |
| AT712/21           | n.a.                     | Essa Commerce Bilisim ve Ithalat Ihracat Tic.A.S. | Bioessa SARS-CoV-2 Antigen Schnelltest  | N                               | 0,0%                       | 0,0%     | 0,0%   | 0,0%  |
| AT899/21           | FRTFT02                  | FAGO MEDIKAL San. Tic. Ltd                        | FAMEX® SARS-CoV-2 Ag Rapid Nasopharyngeal Test Kit                                      | N                               | 20,0%                      | 0,0%     | 0,0%   | 8,0%  |
| AT819/21           | BQ-03012                 | Foregene Co.,Ltd.                                 | FOREGENE SARS-CoV-2 Antigen Test Kit  | N                               | 30,0%                      | 0,0%     | 0,0%   | 12,0%   |
| AT201/20           | ICOV-502                 | Hangzhou AllTest Biotech Co. Ltd.                 | COVID-19 Antigen Rapid Test (Nasopharyngeal swab)                                       | n.a.                            | 16,7%                      | 0,0%     | 0,0%   | 6,0%  |
| AT972/21           | BSK01S1S                 | Hangzhou Bioer Technology Co., Ltd.               | BIOflux SARS-CoV-2 Antigen Test Kit (colloidal gold method)                             | N                               | 60,0%                      | 0,0%     | 0,0%   | 24,0%   |
| AT041/20           | INCP-C81-20              | Hangzhou Biotest Biotech Co., Ltd.                | Lumiratek SARS-CoV-2 Antigen Rapid Test Cassette  | N                               | 29,4%                      | 0,0%     | 0,0%   | 10,0%   |
| AT662/21           | n.a.                     | Hangzhou Fanttest Biotech Co.,Ltd.                | Fanttest Novel Coronavirus(SARS-CoV-2) Antigen Rapid Test Cassette                      | N                               | 0,0%                       | 0,0%     | 0,0%   | 0,0%  |
| AT015/20           | K511416D                 | Hangzhou Realy Tech Co., Ltd.                     | Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)                       | n.a.                            | 58,8%                      | 0,0%     | 0,0%   | 20,0%   |

| AT-Nr. /<br>AT-No.      | Ref-Nr./<br>ID-No. * | Hersteller /<br>Manufacturer                  | Testname /<br>Test name  | Zielantigen /<br>target antigen | Sensitivität / Sensitivity |          |        | Gesamt-<br>Sensitivität /<br>total<br>sensitivity |
|-------------------------|----------------------|---|--|---------------------------------|----------------------------|----------|--------|---|
|                         |                      |   |  |                                 | Cq ≤25                     | Cq 25-30 | Cq ≥30 |   |
| AT088/21                | K590516D             | Hangzhou Realy Tech Co., Ltd.                 | Heinzer Antigen Covid19 Spucktest Schnelltest [Original Name: Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Device (saliva)] | N+S                             | 65,0%                      | 5,0%     | 0,0%   | 28,0%   |
| AT437/21                | n.a.                 | Hangzhou Singclean Medical Products Co., Ltd. | COVID-19 Test Kit (Colloidal Gold Method)  | N                               | 0,0%                       | 0,0%     | 0,0%   | 0,0%  |
| AT160/20                | P211134              | Hangzhou Genesis Biocontrol Co., Ltd          | KaiBiLi COVID-19 Antigen Rapid Test Device   | N                               | 52,9%                      | 0,0%     | 0,0%   | 18,0%   |
| AT1274/21 <sup>1)</sup> | IM-10101-25          | ImmoGnost GmbH                                | Immognost SARS-CoV-2 Antigen Schnelltest   | N                               | 15,0%                      | 0,0%     | 10,0%  | 8,0%  |
| AT139/20                | BCOV-502             | Inzek International Trading B.V               | BIOZEK COVID-19-Antigen-Schnelltestkassette  | n.a.                            | 52,9%                      | 0,0%     | 0,0%   | 18,0%   |
| AT178/20                | n.a.                 | Joinstar Biomedical Technology Co., Ltd       | COVID-19 Antigen Rapid Test (Latex)  | S                               | 0,0%                       | 0,0%     | 0,0%   | 0,0%  |
| AT046/20                | G10313               | Joysbio (Tianjin) Biotechnology Co., Ltd.     | Joysbio SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)   | N                               | 47,1%                      | 4,3%     | 0,0%   | 18,0%   |
| AT487/21                | NCV11                | Koch Biotechnology (Beijing) Co., Ltd.        | COVID-19 Antigen Rapid Test Kit  | N                               | 60,0%                      | 0,0%     | 0,0%   | 24,0%   |
| AT684/21                | n.a.                 | LiClear Biotech (Hangzhou) Co., Ltd.          | SARS-COV-2 Nucleocapsid (N) Antigen Rapid Test (VIDA TEST Rapid Diagnostic Test)   | N                               | 0,0%                       | 0,0%     | 0,0%   | 0,0%  |
| AT400/20                | I00053               | Lionex GmbH                                   | Lionex COVID-19 Ag Rapid Test  | S                               | 0,0%                       | 0,0%     | 0,0%   | 0,0%  |
| AT171/20                | MICOG-502 (B2503)    | Medicon Co., Ltd.                             | Trueline COVID-19 Ag Rapid Test  | N+S                             | 58,8%                      | 4,3%     | 0,0%   | 22,0%   |
| AT007/20 <sup>2)</sup>  | 3011030              | Mexacare GmbH Heidelberg                      | QuickTestCorona COVID-19 Antigen Schnelltest   | N                               | 52,9%                      | 4,3%     | 0,0%   | 20,0%   |
| AT470/20                | 243104D-20           | nal von minden GmbH                           | dedicio Medical Test COVID-19 Ag plus Test   | N                               | 35,3%                      | 0,0%     | 0,0%   | 12,0%   |
| AT1181/21               | 800063-20P           | PRIMA Lab SA                                  | Primacovid Antigen Rapid test  | N                               | 70,0%                      | 0,0%     | 0,0%   | 28,0%   |
| AT013/20                | G61RHA20             | RapiGEN, Inc.                                 | Biocredit COVID-19 Ag  | n.a.                            | 16,7%                      | 0,0%     | 0,0%   | 6,0%  |
| AT302/21                | RCCOVAG              | Redcell Biotechnoloji Anim Sirketi            | COVID-19 Antigen Test  | N                               | 0,0%                       | 0,0%     | 0,0%   | 0,0%  |
| AT036/20                | C34800-100           | Servoprax GmbH                                | Cleartest Corona-Antigen   | n.a.                            | 66,7%                      | 0,0%     | 0,0%   | 24,0%   |
| AT242/21                | SG0010A              | SG Diagnostics Pte Ltd                        | SG Diagnostics COVID-19 Antigen Rapid Test Kit (Colloidal Gold-Based)  | N                               | 50,0%                      | 0,0%     | 0,0%   | 20,0%   |
| AT932/21                | n.a.                 | ShanDong ThinkLabor Biotechnology Co.,Ltd.    | Coronavirus Ag Schnelltest Kassette (Tupfer)   | N                               | 0,0%                       | 0,0%     | 0,0%   | 0,0%  |
| AT777/21                | n.a.                 | Shenzhen Landwind Biotechnology Co., Ltd.     | Landwind SARS-CoV-2 Antigen Test Kit (Colloidal Gold)  | N                               | 55,0%                      | 0,0%     | 0,0%   | 22,0%   |
| AT225/20 <sup>3)</sup>  | SP-SW 106            | Spring Healthcare Services Sp zoo             | SARS-Cov-2 Antigen Rapid Test Cassette (swab)  | N+S                             | 29,4%                      | 0,0%     | 0,0%   | 10,0%   |



| AT-Nr. /<br>AT-No. | Ref-Nr./<br>ID-No. * | Hersteller /<br>Manufacturer   | Testname /<br>Test name   | Zielantigen /<br>target antigen | Sensitivität / Sensitivity |          |        | Gesamt-<br>Sensitivität /<br>total<br>sensitivity |
|--------------------|----------------------|--|---|---------------------------------|----------------------------|----------|--------|---|
|                    |                      |  |   |                                 | Cq ≤25                     | Cq 25-30 | Cq ≥30 |   |
| AT186/20           | COVID19AGVC          | SureScreen Diagnostics Ltd.  | COVID-19 Antigen Rapid Test Cassette                                | N                               | 52,9%                      | 0,0%     | 0,0%   | 18,0%   |
| AT128/20           | n.a.                 | TaiDoc Technology Corporation  | FORA COVID-19 ANTIGEN RAPID TEST                                    | N                               | 27,8%                      | 0,0%     | 0,0%   | 10,0%   |
| AT002/20           | B25SY0E1L            | Unioninvest  | Unibioscience COVID-19 Rapid Antigen Test                           | N                               | 0,0%                       | 0,0%     | 0,0%   | 0,0%  |
| AT315/21           | VS200602             | Vision Biyoteknologi Arastirma Gelistirme Labt. Sist. San ve Tic LTD STI | VISION® SARS-CoV-2 Saliva Antigen Rapid Test Kit                    | N                               | 45,0%                      | 10,0%    | 0,0%   | 22,0%   |
| AT062/20           | VCD05-01-011         | VivaChek Biotech (Hangzhou) Co., Ltd.                                    | VivaDiag SARS-CoV-2 Ag Rapid Test                                   | N                               | 50,0%                      | 0,0%     | 0,0%   | 18,0%   |
| AT294/20           | VCD16-01-011         | VivaChek Biotech (Hangzhou) Co., Ltd.                                    | VivaDiag Pro SARS-CoV-2 Ag Rapid Test                               | N                               | 64,7%                      | 0,0%     | 0,0%   | 22,0%   |
| AT218/20           | FSSA-CK20            | W.H.P.M, Inc.  | First Sign SARS-CoV-2 Antigen Test                                  | N                               | 47,1%                      | 0,0%     | 0,0%   | 16,0%   |
| AT001/21           | n.a.                 | Xiamen Jiqing Biomedical Technology Co., Ltd.                            | Gruenbanka SARS-CoV-2 Antigen detection Kit (colloidal gold method) | N                               | 25,0%                      | 0,0%     | 0,0%   | 10,0%   |
| AT012/21           | n.a.                 | Xiamen Zhongsheng Langjie Biotechnology Co., Ltd                         | Covid-19 Antigen Test Cassette                                      | N                               | 11,8%                      | 0,0%     | 0,0%   | 4,0%  |

#### Abkürzungen und Zeichenerklärung / Abbreviations and explanation of symbols:

Cq = Quantifizierungszyklus / quantitative cycle

n.a. = nicht verfügbar / not available

\* Ref-Nr. oder Katalog-Nummer wie bei Einreichung zur Evaluierung / Ref. No. or catalog number as submitted for evaluation

N = Nukleocapsid Protein / nucleocapsid protein

S = Spike Protein / spike protein

1) Laut Hersteller wurde der Test Mitte April 2022 vom Markt genommen. / According to the manufacturer, the test was withdrawn from the market in mid-April 2022.

2) Laut Hersteller wird der Test seit März 2021 weder produziert noch in Verkehr gebracht. / According to the manufacturer, the test has neither been produced nor marketed since March 2021.

3) Laut Hersteller ist das evaluierte Produkt seit Mai 2021 nicht mehr im Handel; eine Weiterentwicklung des Tests (Zielantigen = N) ist unter demselben Namen und Ref-Nr. verfügbar, dieser ist jedoch in der BfArM Liste unter einer anderen AT-Nummer gelistet. / According to the manufacturer, the evaluated product is no longer on the market since May 2021; a further development of the test (target antigen = N) is available under the same name and ID-No., but is listed in the BfArM list under a different AT number.

**Die Liste dient der Information und erhebt keinen Anspruch auf Vollständigkeit. Änderungen bleiben vorbehalten.**

**The list is for information only and does not claim to be complete. Subject to change without notice.**